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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,902	08/17/2006	Takaji Wakita	1254-0321PUS1	2324

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
04/01/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/589,902	WAKITA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-27* is/are pending in the application.

4a) Of the above claim(s) *12-21 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-11,22 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 2, 5-27 are pending in the application.

2. In the prior action, claims 1-26 were pending, with claims 1-11 and 22 under consideration and rejected; and claims 12-21 and 23-26 withdrawn from consideration.

3. In the Response of March 1, 2009, the Applicant amended claims 1, 5, 22, and 23; cancelled claims 3 and 4; and added claim 27.

4. Claims 1, 2, 5-11, 22, and 27 are under consideration.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on March 1, 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

6. **(Prior Objection- Withdrawn)** The disclosure was objected on the basis of informalities with respect to the disclosure of SEQ ID NO: 12. In view of the amendments to the application and the sequence listing, the objection is withdrawn.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **(Prior Rejection- Withdrawn)** Claim 5 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear if the functional language at the end of subpart (b) was intended to also apply to the RNA of subpart (a) of the claim. In view of the amendments to the claim, the rejection is withdrawn.

9. **(New Rejection-Necessitated by Amendment)** Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim purports to further define claim 5. The claim indicates that the claimed replicon comprises the following RNA (a) or (b), wherein (a) is an RNA comprising a sequence shown in SEQ ID NO: 13, and having the autonomous replication and ability to produce viral particles of that sequence, and (b) is an RNA varying from SEQ ID NO: 13 by addition, deletion, or substitution of 1-10 nucleotides which has the indicated functional characteristics.

Claim 5 itself reads on a replicon according to (a) which comprises the sequence of SEQ ID NO: 13, or (b) which comprises a sequence varying from SEQ ID NO: 13 by 1-30 nucleotides, both of which are required to meet the indicated functional limitations. Because subpart (a) of claim 27 is broader in scope that the subpart (a) of claim 5 (a sequence comprising **a** sequence of SEQ ID NO: 13 compared to a sequence comprising **the** sequence of SEQ ID NO: 13), it is not clear if claim 27 is attempting to redefine claim 5, if subpart (a) of claim 27 is supposed to have any relation to subpart (a) of claim 5, or if claim 27 was merely attempting to further limit the replicon of subpart (b) of claim 5 by limiting the number of nucleotide changes permitted from 30 to 10.

It is suggested that the claim be amended to read on the replicon RNA of claim 5 - - wherein RNA (b) comprises a nucleotide sequence derived from the sequence of SEQ ID NO: 13 by deletion, substitution, or addition of 1 to 10 amino nucleotides- - and to delete any reference to subpart (a).

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Maintained in part)** Claims 1-11 and 22 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected as lacking adequate support for HCV RNA replicons having autonomous replication ability, and optionally having the ability to produce viral particles, which comprise "a sequence" of SEQ ID NO: 13, or which have both these functions and vary from SEQ ID NO: 13 by a limited number of, but otherwise undefined, mutations.

In view of the amendments to the claims, the rejection is withdrawn from claims 1, 2, 6-11, and 22. However, the rejection is maintained over claim 5, and extended to new claim 27 for the reasons of record (i.e. the lack of any identification of nucleotides that must be maintained to retain the required functions of autonomous replication and the ability to produce viral particles, the uncertainty in the art regarding what mutations may be made without a loss of these activities, and the absence of an adequately representative number of species of the claimed genus). While the Applicant asserts that the claims as amended have overcome the rejection, the

Applicant does not provide any argument or evidence as to how the amendments to claim 5 or the limitations of claim 27 meet the concerns raised in the rejection of record.

Claim Rejections - 35 USC § 102

12. **(Prior Rejection- Withdrawn)** Claim 5 was rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. (Gastroenterol 128:1808-17- of record in the March 2007 IDS). In view of the amendment to the claims, this rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claims 5 and 22 were rejected under 35 U.S.C. 102(b) as being anticipated by Blanchard et al. (J Virology, 76:4073-79). In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. **(Prior Rejection- Maintained)** Claims 1-11 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kato et al. (Gastroenterol 128:1808-17- supra) in view of Ikeda et al. (J Virol 76:2997-3006) and of EMBL AB047639. The rejection is withdrawn from cancelled claims 3 and 4; is maintained against amended claims 1, 2, 5-11, 22, and new claim 27.

Applicant's arguments are noted, but are not found persuasive. The Applicant asserts that the Examiner did not follow the Graham inquiry and make a proper rejection. The argument is

not found persuasive as the Examiner set forth the teachings of the prior art, the differences between the art and the claimed invention, and provided a rationale as to why the teachings in the prior art would be combined to render the claimed invention obvious.

The Applicant asserts that the Examiner did not consider the secondary evidence of non-obviousness- i.e. the unexpected ability of the claimed replicons to produce viral particles. This argument is not found persuasive. As was indicated in the prior art, the full-length replicon would have been an obvious variant of the subgenomic replicon disclosed by Kato. While there may be uncertainty in the art as to which HCV genomes would be capable of replication and production of viral particles in cells, there is no evidence of uncertainty in the ability of full-length genomic replicons to replicate where the subgenomic replicon of that HCV isolate has been shown to replicate. Thus, the full-length replicon of the HCV strain JFH-1 was an obvious functional equivalent of the subgenomic replicon disclosed in the Kato reference.

While it may be unexpected that the claimed replicons would produce viral particles, such would be inherent to the obvious use of these replicons in undergoing replication in cells for other purposes- such as screening for anti-viral drugs effective in the inhibition of viral replication of the replicon. Moreover, the courts have indicated that recognition by an Applicant of "another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). See also, MPEP §2145 II. Thus, the fact that the Applicant unexpectedly found an otherwise obvious product to have an additional advantage does not render the product, or obvious uses thereof, non-obvious.

The arguments are therefore not found persuasive, and the rejection is maintained for the reasons above, and the reasons of record.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. **(Prior Rejection- Maintained)** Claims 1-5 and 22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 21 of copending Application No. 10/558155 in view of Ikeda et al. (supra). Applicant traverses the rejection on the basis that the amendments to the claims have overcome the rejection. While the present claims require the use of the full HCV genome in the claimed replicons, and certain of the copending claims require the use of only subgenomic replicons, such is not true for each of the copending claims. See e.g., copending claim 3, which is silent as to the presence of the structural genes. Thus, based on the additional teachings of Ikeda, the present claims still read on obvious embodiments of the copending claims.

The Applicant additionally requests that the rejection be held in abeyance. However, this is not in accordance with Office policy to move forward on prosecution. The rejection is therefore maintained.

Moreover, it is noted that the copending application has an earlier effective filing date than the present application. In such a situation, a terminal disclaimer is required even if the copending application has not yet been allowed. See, MPEP § 804 I.B.1.

This is a provisional obviousness-type double patenting rejection.

19. **(Prior Rejection- Withdrawn)** Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-8 of copending Application No. 11/898468, and over claim 34 of copending application 10/572,476. In view of the amendments to claim 5, this rejection is withdrawn.

Conclusion

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648